## Remarks

Prior to this amendment, claims 1, 2, 4, 6, 7, 9, 11, 12-24, and 38 were pending, of which claim 18 was withdrawn. Claims 6, 11, and 15 are canceled herein. Claims 1, 4, 9, 13, 14, 18, and 24 are amended herein. Support for the amendment of claims 1 and 24 can be found in the specification at least at page 69, lines 18-32; page 17, line 32; and claim 6. Claim 18 is amended to correct matters of form and to parallel the scope of the pending claims.

No new matter is introduced by the foregoing amendments. Applicants expressly reserve the right to pursue subject matter removed from the current claims by amendment in a later application. After entry of this amendment, **claims 1, 2, 4, 7, 9, 12-14, 16-24, and 38 are pending (of which claim 18 continues to be withdrawn).** Consideration and allowance of the pending claims are requested.

*Claim Rejections Under 35 U.S.C. §112, first paragraph*

*A) Written description*

Claims 1-17, 19-24, and 38 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the claims are rejected because "the scope of SUSP-1 variant (95% identity to SEQ ID NO:457) as claimed is not limited to any specific activity of SUSP-1 but broadly encompasses the modulation of angiogenesis via any and all means" and because "the specification fails to disclose a representative number of SUSP-1 species defined by structure and function" (Office action, page 2-3). Applicants respectfully traverse this rejection.

Applicants note that claims 3, 5, 8, 10, and 25-37 were canceled in the Response submitted on June 20, 2007. Thus, Applicants believe that the claim rejections under 35 U.S.C. §112, first paragraph should be directed to claims 1, 2, 4, 6, 7, 9, 11-17, 19-24, and 38 and will respond to the Office action accordingly. Claims 6, 11, and 15 are canceled, rendering the rejection of these claims moot.

Solely to advance prosecution in this case, claim 1 is amended to recite that the effect of the compound upon the SUSP-1 polypeptide "is altered SUSP-1 protease activity and the altered protease activity regulates angiogenesis." Thus, claim 1, as amended, recites both a structure of a SUSP-1 polypeptide (at least 95% identity to SEQ ID NO:457) and two functions of a SUSP-1 polypeptide (protease activity; regulates angiogenesis). In addition, amended claim 1 correlates the effect of altered SUSP-1 protease activity with regulation of angiogenesis.

Also solely to advance prosecution in this case, claim 24 is amended to recite that SUSP-1 has protease activity and regulates cell surface expression of an $\alpha v\beta 3$ protein. In addition, claim 24 is amended to recite an *in vitro* effect and an effect in a cell-based assay. Thus, claim 24, as amended, recites both a structure of a SUSP-1 polypeptide (at least 95% identity to SEQ ID NO:457) and two functions of a SUSP-1 polypeptide (protease activity; regulates cell surface expression of an $\alpha v\beta 3$ protein). In addition, amended claim 1 correlates the effect of altered expression of an $\alpha v\beta 3$ protein with regulation of angiogenesis.

In light of the amendments of claims 1 and 24, Applicants submit that the claims are directed to methods of identifying a compound that modulates angiogenesis using a SUSP-1 polypeptide having specific structure and function. Claims 2, 4, 7, 9, 12-14, 16, 17, 19-23 and 38 depend (directly or indirectly) from claims 1 or 24 and incorporate all of the limitations thereof.

In the current instance, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the polypeptide sequence in SEQ ID NO:457; Applicants had also contemplated and provided explicit written description of polypeptides with at least 95% sequence identity to that sequence (for example, page 29, lines 26-34). Furthermore, the specification describes how to determine which SUSP-1 polypeptide sequences have the claimed activities or functions (for example, page 39, line 8 through page 41, line 6; page 48, line 24 through page 53, line 29; page 69, lines 19-32).

The Office is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id.*

Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision sequences having at least 95% sequence identity to the sequence set forth in SEQ ID NO:457 based on the teachings of the specifications and the provision of SEQ ID NO:457 itself. In addition, the knowledge and level of skill in the art would allow a person of ordinary skill to envision which of these sequences has the claimed activities or functions. Thus, the pending claims, directed to methods of identifying a compound that modulates angiogenesis using a SUSP-1 polypeptide having specific structure and function, are sufficiently described by the specification, and Applicants request that the rejection under 35 U.S.C. §112, first paragraph, as applied to the written description requirement, be withdrawn.

*B) Enablement*

Claims 1, 2, 4, 6, 7, 9, 11, 12-24, and 38 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the claims are rejected because the specification "does not reasonably provide enablement for a method capable of identifying compounds that modulate angiogenesis" and because "the specification fails to disclose a representative number of SUSP-1 species defined by both structure and function." Applicants respectfully traverse this rejection. Claims 6, 11, and 15 are canceled, rendering the rejection of these claims moot.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not undue. *In re Wands* 8 USPQ2d 1400 (Fed. Cir. 1988). A considerable amount of experimentation is permissible, if it is **merely routine**, or

if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.* Applicants submit that any experimentation would be routine and the present application provides the guidance necessary to make and use the sequences encompassed by the claims.

As discussed above, claims 1 and 24 are amended to be directed to a method of identifying a compound that modulates angiogenesis using a SUSP-1 polypeptide having specific structure and function. Applicants respectfully submit that the specification teaches how to make a SUSP-1 polypeptide having at least 95% identity (page 29, line 26 through page 31, line 20) with SEQ ID NO:457. Applicants also submit that the steps required to make a SUSP-1 polypeptide having at least 95% identity with SEQ ID NO: 457 would be well known to one of skill in the art. For example, the use of automated peptide synthesizers was well known to those of skill in the art at the time the subject application was filed. Thus, it would merely be routine to perform the claimed methods using the recited SUSP-1 polypeptides. Moreover, the specification clearly teaches how to determine which SUSP-1 polypeptide sequences have the claimed activities or functions (for example, page 39, line 8 through page 41, line 6; page 48, line 24 through page 60, line 33; page 69, lines 19-32). In addition, the specification teaches which assays known to those of skill in the art can be used to identify potential modulators of angiogenesis regulatory proteins (page 27, line 11-22) and how to test these compounds to determine their efficacy at modulating angiogenesis (page 39, lines 9-28; page 48, line 24 through page 53, line 29). Thus, it also would be merely routine to one of skill in the art to perform the claimed methods to identify a compound that modulates angiogenesis.

In summary, based on the teachings of the specification and the knowledge of one of skill in the art, it would be simply a matter of **routine** to perform the claimed methods using the recited SUSP-1 polypeptides and undue experimentation would not be required. Applicants submit that the claims, as amended, are fully enabled by the specification.

In light of the above arguments, Applicants submit that amended claims 1, 2, 4, 7, 9, 12-14, 16, 17, 19-24, and 38 are fully enabled by the specification. Applicants request that the rejection under 35 U.S.C. §112, first paragraph, as applied to the enablement requirement, be withdrawn.

**Conclusions**

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at (503) 595-5300.

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